PATENT

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

PATENT APPLICATION: DALE R. LOVERCHECK

Serial No. 09/900,647 Art Unit:1617

Filed: July 7, 2001 Examiner: San-Ming Hui

For: UNIT DOSE OF MATERIAL IN SYSTEM AND METHOD

The Commissioner for Patents
Alexandria, Virginia. 22313-1450

REPLY BRIEF

This Reply Brief is in response to the Examiner's Answer mailed November 3, 2004.

THE CLAIMS OF THE GROUPS DO NOT STAND OR FALL TOGETHER

No group of claims, including pending Claims 26-30, 33-35, 37-46, 48-55, 57-74, 76-83, 85-94, stands or falls together. In the Appeal Brief argument and arguments herein, Appellant explains why the claims of the groups are believed to be separately patentable. And, has not merely pointed out differences in what the claims cover, but has provided arguments as to why the claims are separately patentable. Also, in grouping of claims, two statements are included in the Appeal Brief at page 2, that the claims of the groups do not stand or fall together. So, the Board shall not select a single claim from the group and decide the appeal as to the ground of rejection on the basis of that claim alone, 37 CFR 1.192 (c)(7), removed and reserved, 69 FR 49959 August 12, 2004.

[It is noted that the Examiner erroneously states that the Appellant's brief does not include a statement that the claims do not stand or fall together and reasons in support thereof, Examiner's Answer, page 2, paragraph 7.]

OVERVIEW

A nutritional supplement in a unit dose of discomfort reliever is required by Appellant's claims. The claims require indications indicating an amount and percent daily value of the nutritional supplement in a unit dose of discomfort reliever. And, they also require indications indicating the nutritional supplement for supplementing

nutrition in a unit dose of discomfort reliever. These requirements are not disclosed, obvious, or possible from the applied prior art.

It is well know that vitamin C is easily destroyed by exposure to oxygen. SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation and intended to be oxidized. So, it is oxidized at unknown rates to unknown amounts of unknown nutrition-supplementing function. These unknown amounts cannot be predetermined or indicated as an amount and a percent daily value. Thus, indicating them is not conventional, obvious, or possible. But, an amount and a percent daily value must be indicated for a nutritional supplement. So, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose a nutritional supplement, within the scope of Krause, 21 USC 321 and 21 CFR 101.36 and Appellant's claims.

Unprotected antioxidant and stable nutritional supplement formulations of vitamin C are not chemically identical, and their nutrition-supplementing properties and functions are not the same. And, substituting the antioxidant formulation for the nutritional supplement formulation substantially changes and completely obliterates the indicating functions of the invention. It erroneously assumes that an indicated stable known amount of vitamin C is identical to unknown oxidizing amount(s) that cannot be indicated. And, it disregards the continual loss in effectiveness of the inherent nutrition-supplementing property and function of vitamin C due to its ongoing oxidation. The effectiveness of the nutrition-supplementing property and function of vitamin C is inseparable from its amount. So, when the amount of vitamin C is not known, its nutrition-supplementing property and function are not known either.

SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation and intended to be oxidized. So, vitamin C is oxidized unpredictably to unknown amounts that cannot be predetermined or indicated in products based on them. Oxidized vitamin C is not chemically identical to vitamin C. Its properties are not the same as vitamin C. And, its functions are not the same as vitamin C. SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose indicating supplementing nutrition or any intention of

supplementing nutrition. They do not disclose a percent daily value for vitamin C. They do not disclose indicating an amount of vitamin C or indicating a percent daily value for vitamin C. They do not disclose a vitamin C formulated as a nutritional supplement, an amount of vitamin C that can be indicated, or vitamin C formulated as used by Appellant's claimed invention.

SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation and intended to be oxidized. It is continually oxidized, so its amount continually decreases and cannot be indicated. Thus they teach away from formulating a stable amount of vitamin C as a nutritional supplement. And they teach away from indicating it as an amount and percent daily value of nutritional supplement for supplementing nutrition. And, they do not disclose any teaching to suggest their combination with Krause. Thus, the applied prior art teaches away from the feature of Appellant's claims of a nutritional supplement in a unit dose of discomfort reliever. It teaches away from indicating an amount and percent daily value of nutritional supplement in a unit dose of discomfort reliever. And, it teaches away from indicating an amount of nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever.

Printed matter may well constitute limitations upon which patentability can be predicated. Indicating an amount (and percent daily value) of vitamin C is related to its new formulation as a stable amount of nutritional supplement in a unit dose of discomfort reliever that is indicated. Vitamin C formulated as a nutritional supplement and indicated by its amount and percent daily value in a unit dose of discomfort reliever is unexpectedly superior to the prior art. It requires only half of the number of compositions and containers required by the prior art. It is not taught by the prior art. And, it is not obvious from the prior art. So, it is matter that constitutes limitations upon which patentability can be predicated. The PTO must consider all claim limitations, when determining patentability of an invention over the prior art, and may not disregard claim limitations comprised of printed matter. A printed matter rejection under section 103 stands on questionable legal and logical footing.

The rejection is erroneous because it assumes that discomfort reliever labeling would include indications indicating supplementing nutrition and percent daily value, which are neither disclosed in the applied prior art or prior commercial labeling, nor mandated by drug, food or dietary supplement labeling laws. And, it erroneously asserts that it would be obvious to include indications indicating supplementing nutrition and percent daily value in a hypothetical drug label for a theoretical product, which is not intended to supplement nutrition. Thus, the rejection is unsupported, and inconsistent with the applied prior art, the law and prior commercial labeling of record.

The combination of references is not proper, because nothing is taught in them to suggest their combination. It does not meaningfully consider all of the limitations of the claims. It substantially changes and completely obliterates the indicating function of the invention. So, it does not have a reasonable expectation of success. And, it is based on forbidden hindsight. Also, SS Pharmaceutical, Tsunoda, and Yeh et al teach away from Appellant's invention.

Appellant's invention provides the same discomfort relief, but with improved ability to self-regulate consumption of nutritional supplements over the prior art. Thus, it retains all of the functions of the prior art, while it omits half of the number of its compositions and containers. These are data of superior results, and indicia of unobviousness, over the prior art. So, patentability is shown beyond the requirements of the statute. Given the similar compositions of SS Pharmaceutical, Tsunoda and Yeh et al to those useful in Appellant's invention, the substantially improved results of Appellant's invention are *ipso facto* unexpected.

There is simplicity of the new invention, given the similarity of the compositions of SS Pharmaceutical, Tsunoda, and Yeh et al to those useful in Appellant's invention. But, the simplicity of a new invention is often the very thing that is not obvious before it is made.

A NUTRITIONAL SUPPLEMENT IS NOT DISCLOSED BY SS PHARMACEUTICAL, TSUNODA, AND YEH ET AL

The Examiner notes that vitamin C is known to be useful in nutritional supplement formulations (Examiner's Answer page 6). But, for vitamin C to be

useful as a nutritional supplement, it must be formulated so that a stable amount can be indicated. It must be intended to supplement nutrition; it must be indicated for supplementing nutrition; and its quantitative amount and percent daily value must be indicated on its label, as required of nutritional supplements by 21 CFR 101.36(b)(ii)(A) and 21 CFR 101.36(b)(iii): Exhibit D, of the Amendment filed May 19, 2004; 21 USC 321 (a)(ff)(1) and 21 USC 321 (a)(ff)(2)(C): Exhibit E, of the Amendment filed April 1, 2004, Krause, and Appellant's claims. By contrast, SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation. It is intended to be oxidized, and it decreases to unknown amount(s) as it is oxidized. Unknown amount(s) cannot be indicated as an amount or percent daily value, as required for nutritional supplements by 21 CFR101.36; Krause; and Appellant's claims. And, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose any intention of supplementing nutrition or indicating supplementing nutrition, as required of nutritional supplements by 21 USC 321, Krause, and Appellant's claims. Also, there is no teaching to suggest their combination with Krause, so it is improper. Thus, formulating vitamin C to be useful as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims is not obvious from the applied prior art. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being obvious over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

Optimizing our daily intake of vitamins and minerals ensures optimal health, APPENDIX E, pages 27-28. An amount (60mg) of vitamin C is recommended and essential daily for supplementing nutrition, Lieberman and Bruning, The Real Vitamin & Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004 and 21 CFR 101.9(c)(8)(iv). And, a nutritional supplement for supplementing nutrition requires indications indicating its amount and percent daily value, 21 CFR 101.36, Exhibit D, of the Amendment filed May 19, 2004, and as required by Appellant's claims. These indications may be presented in Nutrition Facts 21 CFR 101.9(c)(11)-(14). And, they

indicate to a consumer that the indicated amount and percent daily value of the essential nutritional supplement may be consumed until the expiration date, 21 CFR 211.137(a): APPENDIX A.

Exposure to oxygen easily destroys vitamin C, and this process is accelerated by light and heat, Lieberman and Bruning, The Real Vitamin & Mineral Book, page 126, 1997 Appeal Brief, APPENDIX B. The role of the antioxidant is to provide an alternative path for oxidation, so it is continually oxidized and decreases in amount, Parker, Encyclopedia of Science and Technology, Antioxidant: page 124, APPENDIX B. Thus, antioxidant is destroyed in the process and does not function indefinitely, Parker, page 124, APPENDIX B. An antioxidant is formulated to be consumed by oxidation, to prevent oxidation of an oxidation sensitive compound, as see Fukamachi et al US Patent 4,929,774 column 1, lines 9-22 and TABLES I-III, columns 9 and 10 APPENDIX C. [It is noted that all of the examples of Yeh et al and example 3 of Fukamachi et al use tocopherol (a vitamin E compound) as antioxidant.] For example, vitamin A formulated as an antioxidant decreased to thirteen percent (13%) remaining in four weeks at a constant 40°C and constant seventy percent (70%) relative humidity, Fukamachi et al US Patent 4,929,774 Example 2-29, column 9, APPENDIX C.

So, an antioxidant, such as vitamin C formulated without protection from oxidation as an antioxidant decreases continually to unknown amounts, varying with the temperature, humidity and light during storage. And these unknown amount(s) cannot be predetermined or indicated as an amount for consumption by a consumer. Thus, vitamin C must be protected from oxidation, if its amount is to be stable, so that it can be indicated, until the expiration date. To formulate vitamin C to maintain its amount against oxidation, antioxidants may be added, as disclosed by Hermelin et al US Patent 6,576,666 column 12, lines 53-57 APPENDIX D. Nutrition supplementing material may be dried to contain 4 percent or less of moisture and it may contain complexing agents, as disclosed by Fuckamachi et al US Patent 4,929,774, Abstract, column 2, lines 1-7 and Examples 1-6, columns 4-8: APPENDIX C.

Neither, SS Pharmaceutical, Tsunoda nor Yeh et al disclose antioxidants,

complexing agents, or drying to maintain the amount of vitamin C. They disclose vitamin C formulated as an antioxidant with ibuprofen anti-inflammatory to synergistically reduce pain or inflammation. They do not disclose protecting an amount of vitamin C against oxidation or indicating its amount. They do not disclose any intention of supplementing nutrition. And, they do not disclose indicating a nutritional supplement by its amount and percent daily value, as required of nutritional supplements by 21 USC 321 (a)(ff)(1); 21 USC 321 (a)(ff)(2)(C): Exhibit E, of the Amendment filed April 1, 2004; 21 CFR 101.36: Exhibit D, of the Amendment filed May 19, 2004, Krause, and Appellant's claims. And, there is no teaching to suggest their combination with Krause, so the rejection is improper, as discussed below. Thus, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, indicating an amount and percent daily value of a nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever, as required by Appellant's claims, is not be obvious from the applied prior art. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being obvious over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

INDICATING AN AMOUNT IS A FUNCTION OF ITS BEING CONSTANT

The Examiner states that there is no functional relationship between the ingredients and the label, Examiner's Answer, pages 5-7, 11, 12, 14 and 16-25. But, the indicating function is related to the stability of the amount of vitamin C to be indicated. The invention requires indicating an amount of vitamin C in a unit dose of a discomfort reliever. For an amount of vitamin C to be indicated it must be protected from oxidation to prevent it from oxidizing and decreasing to unknown amount(s). And, to be a nutritional supplement, it must be indicated as an amount and percent daily value, as required by 21 CFR101.36 and as claimed by Appellant.

Thus, for vitamin C to be formulated as a nutritional supplement, it must be protected so that it is not oxidized. And, its quantitative amount and percent daily value must be indicated on its label, as required by 21 CFR101.36(b)(ii)(A) and 21 CFR101.36(b)(iii): Exhibit D, of the Amendment filed May 19, 2004 and

21 CFR 211.137(a): APPENDIX A. It is easily destroyed by exposure to oxygen, and this process is accelerated by light and heat, Lieberman and Bruning, The Real Vitamin & Mineral Book, page 126, 1997 Appeal Brief, APPENDIX B. Oxidation causes it to continually decrease to unknown amount(s), and unknown nutrition- supplementing function(s) Parker, Encyclopedia of Science and Technology, Antioxidant: page 124, APPENDIX B. And, an amount of vitamin C, which is not protected, is continually oxidized and decreases at unpredictable rates to unknown amount(s) that cannot be indicated as an amount and percent daily value of nutritional supplement, as required by 21 CFR 101.36 and as claimed by Appellant.

And, a nutritional supplement and indicating an amount of a nutritional supplement are not disclosed by or obvious from SS pharmaceutical, Tsunoda, and Yeh et al. They disclose vitamin C formulated without protection from oxidation as an antioxidant with ibuprofen anti-inflammatory to synergistically reduce pain or inflammation, Yeh et al column 2, lines 41-45, Tsunoda, Abstract and SS pharmaceutical. Since, it is not protected from oxidation it is continually oxidized to unknown amount(s), and unknown nutrition-supplementing function(s). It is not formulated as a nutritional supplement, that must be indicated by an amount, to be within the scope of 21 CFR 101.36: Exhibit D, of the Amendment filed May 19, 2004 and 21 CFR 211.137(a): APPENDIX A and as claimed by Appellant.

An element substituted for an element in a claim must not be such as would substantially change the way in which the function of the invention is performed, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). But, in products based on SS Pharmaceutical, Tsunoda and Yeh et al, vitamin C is formulated as an antioxidant. It is not protected from oxidation. Thus, it decreases due to oxidation to unknown nutrition-supplementing function(s) and unknown amount(s) that cannot be predetermined or indicated. Consequently, substituting the vitamin C formulation of SS Pharmaceutical, Tsunoda, and Yeh et al, for the nutritional supplement formulation of the invention, substantially changes (completely obliterates) the

indicating function of the invention, so it cannot be performed. Thus, the rejection is improper, Perkin – Elmer Corp.

The court has stated that a teaching is required in the references to suggest the combination thereof for a proper combination of references, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983). And, this teaching to make the claimed combination and a reasonable expectation of success must both be found in the prior art, not in Appellant's disclosure In re Vaeck 947 F 2d 488, 20 USPQ2d 1438 (Fed. Cir 1991). SS pharmaceutical, Tsunoda and Yeh et al disclose vitamin C formulated without oxidation protection as an antioxidant in medications. It oxidizes and decreases to unknown nutrition-supplementing function(s) and unknown amount(s) that cannot be predetermined or indicated as required to be a nutritional supplement. Krause discloses vitamin C formulated as a nutritional supplement and indicating its amount for nutrition labeling. No teaching is provided by SS Pharmaceutical, Tsunoda, Yeh et al or Krause to suggest their combination, so the combination is improper (Appeal Brief pages 2-6). Thus, the prior art rejection is improper because it lacks both a teaching to make the claimed combination and a reasonable expectation of success, since it substantially changes (completely obliterates) the way in which the indicating function of the invention would be performed, In re Sernaker, In re Vaeck and Perkin – Elmer Corp.

Prior art teachings away from the invention, support a conclusion of nonobviousness, Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990). SS Pharmaceutical, Tsunoda, and Yeh et al teach away from formulation of vitamin C as a stable nutritional supplement, by their disclosure of vitamin C formulated without oxidation protection as an antioxidant with ibuprofen anti-inflammatory to synergistically reduce pain or inflammation (Appeal Brief, page 15-16). A formulation of vitamin C without oxidation protection as an antioxidant is not a formulation as a stable nutritional supplement. Antioxidants that are not protected from oxidation, continually decrease to unknown amount(s), that cannot be indicated as a predetermined amount as required to be a nutritional supplement, 21 CFR 101.36. Thus, they teach away from formulating vitamin C to maintain and indicate its amount, as required to be a nutritional supplement, and by Appellant's claims.

And, they teach away from (and discourage) indicating a predetermined amount of nutritional supplement in a unit dose of a discomfort reliever, as required by Appellant's claims, which supports a conclusion of nonobviousness, Dow Chemical Co.

Furthermore, SS Pharmaceutical, Tsunoda, and Yeh et al disclosing ascorbic acid as an antioxidant to reduce pain, inflammation and/or periodontal disease. They do not disclose supplementing nutrition. And, by disclosing vitamin C formulated without oxidation protection as an antioxidant, they teach away from formulating it as a stable nutritional supplement and indicating supplementing nutrition. Vitamin C is easily oxidized, and they do not disclose protecting it oxidation. Thus, it decreases due to oxidation to unknown amount(s) and unknown nutrition-supplementing properties that cannot be indicated. So, they teach away from the function of indicating a predetermined amount of a nutritional supplement for supplementing nutrition, as required by Appellant's claims.

It is legal error to use the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir. 1990). In constructing the rejection the Examiner combines SS Pharmaceutical, Tsunoda, Yeh et al and Krause without any teaching in the references for the combination thereof. The Examiner has made legally erroneous use of Appellant's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann.

Also, each vitamin is essential to good health regardless of how much of anything else is consumed, Lieberman and Bruning, The Real Vitamin & Mineral Book, 1997, page 17: EXHIBIT A of the Supplemental Remarks filed May 19, 2004. By, disclosing that a vitamin (vitamin A) functions the same as a compound that is not a vitamin, Yeh et al teach away from the function of indicating a nutritional supplement for supplementing nutrition, (Appeal Brief, page 15). They are teaching that neither vitamin A, nor anything else is intended to supplement nutrition. And, they are teaching that the lack of anything that could function and be indicated as a

vitamin is suitable. Thus, Yeh et al teach away from the function and indication of supplementing nutrition. So, it is not obvious to indicate supplementing nutrition by ascorbic acid in a product based on Yeh et al.

Indicating an amount and percent daily value of vitamin C in a unit dose of a discomfort reliever are not disclosed by the applied prior art. Substituting the vitamin C formulation of SS Pharmaceutical, Tsunoda, and Yeh et al, for that of the invention, substantially changes the way in which the indicating function of the invention would be performed, so that it cannot be performed. Thus, the rejection is improper, Perkin – Elmer Corp. Also, the combination of the applied prior art lacks both a teaching to make the claimed combination and a reasonable expectation of success, so it is improper, In re Sernaker and In re Vaeck. SS Pharmaceutical, Tsunoda and Yeh et al teach away from formulating vitamin C as a nutritional supplement. And, they teach away from indicating an amount and percent daily value of a nutritional supplement as required by Appellant's claims, which supports a conclusion of nonobviousness, Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990). Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Thus, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, it is not obvious from the applied prior art to indicate an amount and percent daily value of a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

VITAMIN C FORMULATED AS UNPROTECTED ANTIOXIDANT DECREASES TO UNKNOWN AMOUNT(S) THAT CANNOT BE INDICATED

For vitamin C to be a nutritional supplement, its amount and percent daily value must be indicated, and it must be intended to supplement nutrition, as required by 21 CFR 101.36; 21 USC 321, and Appellant's claims. But, vitamin C is formulated without oxidation protection as an antioxidant and is oxidized to unknown

amounts in products based on SS Pharmaceutical, Tsunoda, and Yeh et al. So, its amount and a percent daily value cannot be predetermined or indicated. Also, they do not disclose any intention of supplementing nutrition. Thus, they do not disclose vitamin C formulated as it is known to be useful as a nutritional supplement. Because, to be useful as a nutritional supplement, vitamin C must be formulated so that its amount and percent daily value can be indicated, as required by 21 USC 321: Exhibit E, of the Amendment filed April 1, 2004 and 21 CFR 101.36: Exhibit D, of the Amendment filed May 19, 2004. And, SS Pharmaceutical, Tsunoda and Yeh et al are not properly combined with Krause, as discussed below. Thus, the applied prior art does not disclose vitamin C formulated so it can be indicated by an amount and percent daily value in a unit dose of discomfort reliever, as required by Appellant's claims. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, it is not obvious from the applied prior art to indicate a predetermined amount and percent daily value of a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that the prior art teaches the composition and amount, Examiner's Answer, pages 17 and 23. But, the prior art does not teach an amount of a nutritional supplement in a unit dose of discomfort reliever, as claimed by Appellant. And, for an amount of vitamin C to be a nutritional supplement that amount and its percent daily value must be indicated, and it must be intended to supplement nutrition, as taught by Krause and as required by 21 CFR 101.36; 21 USC 321 and Appellant's claims. Vitamin C formulated without oxidation protection as an antioxidant oxidizes to unknown amount(s) and unknown properties that cannot be predetermined or indicated. So an amount of vitamin C and its percent daily value cannot be predetermined or indicated for its formulation as an unprotected antioxidant in products based on SS Pharmaceutical, Tsunoda and Yeh et al. Also, they do not disclose any intention of supplementing nutrition, or any

teaching to suggest their combination with Krause. Thus, the applied prior art does not teach vitamin C formulated so that it can be predetermined or indicated by an amount and percent daily value in a unit dose of discomfort reliever as is required to be a nutritional supplement, by 21 CFR 101.36; 21 USC 321 and as is required by Appellant's claims. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. Indicating an amount and percent daily value of a nutritional supplement in a unit dose of discomfort reliever, is not obvious from the applied prior art, as required by Appellant's claims. And, indicating a nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever, is not obvious from the applied prior art as required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that the statement that SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose a nutritional supplement is not based on fact, (Examiner's Answer page 8). But, this statement is based on the fact that an unknown amount of vitamin C cannot be indicated. So, it cannot be a nutritional supplement. This statement is based on the fact that vitamin C is formulated without oxidation protection as an antioxidant in SS Pharmaceutical, Tsunoda and Yeh et al. And, the fact that an unprotected antioxidant is oxidized to unknown amounts having unknown properties that cannot be indicated. So, it cannot be a nutritional supplement. This statement is based on the fact that SS Pharmaceutical, Tsunoda and Yeh et al do not disclose any intention of supplementing nutrition. So, vitamin C disclosed by them as an unprotected antioxidant cannot be a nutritional supplement. And they are not properly combined with Krause.

To be a nutritional supplement, a quantitative amount of vitamin C must be known and intended to supplement nutrition, and that amount and its percent daily value must be indicated, as taught by Krause and as required by 21 USC 321: Exhibit E, of the Amendment filed April 1, 2004 and 21 CFR 101.36: Exhibit D, of the Amendment filed May 19, 2004 and Appellant's claims. And, by disclosing vitamin

C formulated without oxidation protection as an antioxidant, SS Pharmaceutical, Tsunoda and Yeh et al teach away from its formulation as a stable nutritional supplement. Also, they do not disclose a teaching to suggest their combination with Krause. Thus, the applied prior art does not disclose a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, it teaches away from a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. Indicating a nutritional supplement, its amount and percent daily value in a unit dose of discomfort reliever, is not obvious from the applied prior art as required by Appellant's claims. And, indicating a nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever is not obvious from the applied prior art, as required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being obvious over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that vitamin C is well known as nutritional supplement. But, vitamin C is well known to be easily destroyed if it is not protected from oxidation. Exposure to oxygen easily destroys vitamin C, Lieberman and Bruning, The Real Vitamin & Mineral Book, page 126, 1997 Appeal Brief, APPENDIX B. And, protecting vitamin C from oxidation is not disclosed by SS Pharmaceutical, Tsunoda and Yeh et al. Formulating vitamin C without protection from oxidation as an antioxidant teaches away from formulating it as a nutritional supplement. Vitamin C is well known as a nutritional supplement when it is a stable known amount intended to supplement nutrition, and it is indicated by its amount and percent daily value, as taught by Krause and as required by 21 CFR 101.36; 21 USC 321 and Appellant's claims. By contrast, vitamin C formulated without oxidation protection as an antioxidant is oxidized at unknown rates to unknown amount(s) and unknown properties that cannot be predetermined or indicated as an amount and percent daily value. And, SS Pharmaceutical, Tsunoda and Yeh et al disclose vitamin C formulated

without oxidation protection as an antioxidant. And, they do not disclose any intention of supplementing nutrition. So, they do not disclose vitamin C formulated as a nutritional supplement. And they do not disclose a teaching to suggest their combination with Krause. Thus, the applied prior does not disclose (and teaches away from) vitamin C formulated as a well known nutritional supplement that can be predetermined and indicated by an amount and percent daily value in a unit dose of discomfort reliever, as required by Appellant's claims. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. Indicating an amount and percent daily value of vitamin C in a unit dose of discomfort reliever is not obvious from the applied prior art, as required by Appellant's claims. And, indicating a nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever is not obvious from the applied prior art, as required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being obvious over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

The Examiner states that vitamin C is a nutritional supplement regardless of intended use. But, vitamin C is not a nutritional supplement regardless of its intended use as an antioxidant without protection from oxidation. An antioxidant without protection from oxidation is oxidized to unknown amount(s) with unknown properties that cannot be predetermined or indicated. And, for vitamin C to be a nutritional supplement it must be intended to supplement nutrition and it must be labeled as a nutritional supplement by its amount and percent daily value, as taught by Krause and as required by 21 USC 321; 21 CFR 101.36 and Appellant's claims. SS Pharmaceutical, Tsunoda and Yeh et al disclose vitamin C formulated without oxidation protection as an antioxidant. Antioxidants without protection from oxidation are oxidized to unknown amount(s) having unknown properties that cannot be predetermined or indicated as an amount and percent daily value, as required to be a nutritional supplement by 21 USC 321; 21 CFR 101.36 and Appellant's claims. And, SS Pharmaceutical, Tsunoda and Yeh et al

do not disclose any intention of supplementing nutrition, as is required to be a nutritional supplement by 21 USC 321; and Appellant's claims. So, they do not disclose a nutritional supplement. And, vitamin C is not formulated as a nutritional supplement regardless of its intended use as an unprotected antioxidant. Also, they do not disclose a teaching to suggest their combination with Krause. So, it is not obvious from the applied prior art regardless of intended use of vitamin C as an unprotected antioxidant to indicate it as supplementing nutrition in a unit dose of discomfort reliever, as required by Appellant's claims. And, it is not obvious from the applied prior art to formulate vitamin C as nutritional supplement and indicate its amount and percent daily value in a unit dose of discomfort reliever, as required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

And, the Examiner states that the prior art teaches vitamin C as used by Appellant's claimed invention, Examiner's Answer pages 14, 15, 18, 19 and 23-24. But, the prior art does not teach vitamin C formulated as nutritional supplement in a unit dose of discomfort reliever as used by Appellant's claimed invention. For vitamin C to be used as it is used by Appellant's claimed invention, it must be formulated and used as a nutritional supplement. Appellant's claimed invention requires a nutritional supplement indicated by its predetermined amount and percent daily value in a unit dose of discomfort reliever. A nutritional supplement is indicated by its quantitative amount and percent daily value, as required by 21 USC 321 (a)(ff)(1); 21 USC 321 (a)(ff)(2)(C): Exhibit E, of the Amendment filed April 1, 2004; 21 CFR 101.36: Exhibit D, of the Amendment filed May 19, 2004, Krause, and Appellant's claims. But, vitamin C cannot be indicated by an amount or percent daily value in products based on SS Pharmaceutical, Tsunoda and Yeh et al. They teach vitamin C formulated without oxidation protection as an antioxidant. Antioxidants without protection from oxidation are oxidized to unknown amount(s) having unknown properties that cannot be predetermined or indicated by an amount or

percent daily value. And, Krause is not properly combined with them. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as used by Appellant's claimed invention. And, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement and indicate its amount and its percent daily value in a unit dose of discomfort reliever, as used and required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

SS Pharmaceutical, Tsunoda and Yeh et al teach vitamin C formulated as an unprotected antioxidant. They do not disclose protecting it from oxidation. So, it is oxidized to unknown amount(s), and unknown properties that cannot be predetermined or indicated by an amount or percent daily value. Consequently, they do not disclose a nutritional supplement, which must have its amount and percent daily value indicated, as required by, 21 CFR 101.36 Exhibit D, of the Amendment filed May 19, 2004, and Appellant's claims. And, they do not disclose any intention of indicating supplementing nutrition. So, they do not disclose a nutritional supplement, because a nutritional supplement is intended to supplement nutrition and is indicated as an amount and percent daily value of nutritional supplement, as required by 21 USC 321 (a)(ff)(1) and 21 USC 321 (a)(ff)(2)(C), Exhibit E of the Amendment dated April 1, 2004 and Appellant's claims.

A stable amount of vitamin C indicated by that amount, and its percent daily value for a time of use before an expiration date are required to be a nutritional supplement by 21 CFR 101.36 Exhibit D, of the Amendment filed May 19, 2004 and 21 CFR 211.137(a), APPENDIX A, as discussed in the Appeal Brief at pages 4, 21-28; as disclosed at page 6 of the above captioned patent application; and as claimed by Appellant. To formulate vitamin C to maintain its amount, antioxidants may be added, as disclosed by Hermelin et al US Patent 6,576,666 column 12, lines 53-57, APPENDIX D. Indicating (labeling) is needed to indicate a quantitative amount and percent daily value of vitamin C for it to be used as a nutritional supplement, 21

CFR101.36(b)(ii)(A) and 21 CFR101.36(b)(iii): Exhibit D, of the Amendment filed May 19, 2004 and 21 CFR 211.137(a), APPENDIX A. And, the indicated amount is to remain until the expiration date. Without these indications the consumer does not know whether a sufficient amount and percent of a daily value of an essential nutritional supplement is being consumed. Vitamin C formulated as an unprotected antioxidant oxidizing to unknown amount(s) is not a stable amount that can be indicated, as required to be a nutritional supplement by 21 CFR101.36 and as required by Appellant's claims. And, it is neither a known nutritional supplement, nor nutritional supplement regardless of intended use as an unprotected antioxidant. And, it is not useful as a nutritional supplement in Appellant's claimed invention, because it cannot be indicated as a predetermined amount and percent daily value.

Vitamin C formulated without protection from oxidation as an antioxidant with ibuprofen anti-inflammatory to synergistically reduce pain or inflammation, is disclosed in Yeh et al column 2, lines 31-45, Tsunoda, Abstract and SS pharmaceutical. Formulated as an unprotected antioxidant, vitamin C is easily destroyed by exposure to oxygen, and this process is accelerated by light and heat, Lieberman and Bruning, The Real Vitamin & Mineral Book, page 126, 1997 Appeal Brief, APPENDIX B. Vitamin C continually and un-predictably decreases in amount, when it is not protected from oxidation, as see Fukamachi et al US Patent 4,929,774 TABLES I-III, columns 9 and 10 APPENDIX C. So, vitamin C formulated as an unprotected antioxidant continually and un-predictably decreases to unknown amount(s) due to oxidation, Parker, Encyclopedia of Science and Technology, Antioxidant: page 124, APPENDIX B. Vitamin C destroyed by oxidation does not have the nutrition supplementing properties of vitamin C. Thus, vitamin C formulated as an unprotected antioxidant oxidizes to unknown amount(s) having unknown properties, that are not useful or intended to be indicated as a nutritional supplement. And, they cannot be indicated, as required by 21 CFR 101.36(b): Exhibit D, of the Amendment filed May 19, 2004, and as claimed by Appellant.

SS pharmaceutical discloses a "high level" of vitamin C, last two lines. It discloses ibuprofen with vitamin C as a painkiller cold medication (first paragraph). SS pharmaceutical does not disclose protecting vitamin C from oxidation or

indicating an amount of vitamin C. It does not disclose indicating a percent daily value of vitamin C, as required by Appellant's claims. And, SS pharmaceutical does not disclose a nutritional supplement for supplementing nutrition, as required by Appellant's claims. SS pharmaceutical does not disclose stabilizing an amount of vitamin C to prevent its oxidation. So, vitamin C is continually and unpredictably oxidized to unknown amount(s) having unknown properties. These unknown and unpredictable amount(s) and their unknown percent daily value(s) cannot be predetermined or indicated, as required by Appellant's claims. And, SS pharmaceutical does not disclose any intention of supplementing nutrition, as required to be a nutritional supplement. So, vitamin C continually and unpredictably oxidizing to unknown amount(s) having unknown properties is not a nutritional supplement as required by 21 USC 321: Exhibit E, of the Amendment filed April 1, 2004 and 21 CFR 101.36, and as claimed by Appellant. Thus, it is not obvious from the SS pharmaceutical to formulate vitamin C as a nutritional supplement, or to indicate its amount(s) and its percent daily value(s) in a unit dose of discomfort reliever, as used by Appellant's claims.

Yeh et al disclose antioxidants to reduce oxidation of arachidonic acid by competing for oxygen radicals resulting in a decrease in inflammation, column 2, lines 31-38. They disclose 0.01 to 10 % by weight antioxidant (which may be vitamin C) to inhibit prostaglandin formation for treatment of periodontal disease, column 1, lines 6-10 and 65-68; and column 2, lines 1-65. Antioxidant in combination with an anti-inflammatory (which may be ibuprofen) is for synergistic treatment of inflammatory disease, column 2, lines 41-48. Yeh et al disclose the use of antioxidants to reduce oxidation of arachidonic acid, to inhibit prostaglandin formation, and to decrease inflammation for synergistic treatment of periodontal disease. Yeh et al does not disclose protecting an antioxidant from oxidation or indicating an amount of any antioxidant. Yeh et al does not disclose indicating a percent daily value of any antioxidant. They do not disclose any intention of supplementing nutrition. They do not disclose a nutritional supplement for supplementing nutrition, as required by Appellant's claims. And,

they do does not disclose a discomfort or indicating relief for a discomfort, as claimed by Appellant.

Yeh et al does not disclose stabilizing an amount of antioxidant to prevent its oxidation. So, the antioxidant is continually and unpredictably oxidized to unknown amount(s) having unknown properties that cannot be indicated. So, an amount and percent daily value cannot be indicated for a product of Yeh et al, as required to be a nutritional supplement by 21 CFR 101.36; and 21 USC 321 and as required by Appellant's claims. Thus, it is not obvious from the Yeh et al to formulate vitamin C as a nutritional supplement, or to indicate its amount and its percent daily value in a unit dose of discomfort reliever, as required by Appellant's claims.

Tsunoda discloses a synergistic effect against pain for vitamin C with ibuprofen (Abstract). Tsunoda discloses (A) ibuprofen and (B) vitamin C, preferably 0.1-1.1 pt wt component B based on 1 pt. wt. component A, last paragraph. Tablets are prepared preferably by separately preparing granules of the components A and B, mixing calcium ascorbate, for direct tableting, a talc, and magnesium stearate with these granules and tableting, last paragraph. Tsunoda does not disclose any intention of supplementing nutrition.

Tsunoda does not disclose indicating an amount of vitamin C. Tsunoda does not disclose indicating a percent daily value of vitamin C. Tsunoda does not disclose vitamin C as a nutritional supplement for supplementing nutrition, as claimed by Appellant. Tsunoda does not disclose a stabile amount of vitamin C protected from oxidation. And, Tsunoda does not disclose protecting vitamin C from oxidation, so it continually and unpredictably oxidizes decreasing to unknown amount(s) having unknown properties. These unknown amount(s), and their unknown percent daily value(s) cannot be predetermined or indicated, as required for nutritional supplements by 21 CFR 101.36; and 21 USC 321 and as required by Appellant's claims. Thus, it is not obvious from the Tsunoda to formulate vitamin C as a nutritional supplement, or to indicate its amount and its percent daily value in a unit dose of discomfort reliever, as required by Appellant's claims.

Thus, SS pharmaceutical, Tsunoda and Yeh et al disclose vitamin C formulated without oxidation protection as an antioxidant that continually decreases in amount due to oxidation. So, it decreases to different amounts having different properties at different times and cannot be indicated as a predetermined amount, as required to be a nutritional supplement by 21 CFR 101.36: Exhibit D, of the Amendment filed May 19, 2004 and Appellant's claims. And, this teaches away from (and discourages) formulating a stable amount of vitamin C as a nutritional supplement. And, it teaches away from indicating an amount of vitamin C in products based on them. Continually and unpredictably decreasing unknown amounts and unknown percent daily values of vitamin C cannot be indicated. Thus, it is not obvious from the SS pharmaceutical, Tsunoda and Yeh et al to formulate vitamin C as a nutritional supplement, or to indicate its amount and its percent daily value in a unit dose of discomfort reliever, as required by Appellant's claims.

For vitamin C to be a nutritional supplement its amount and percent daily value must be indicated, 21 CFR 101.36, and it must be intended to supplement nutrition, 21 CFR101.36; 21 USC 321: Exhibit E, of the Amendment filed April 1, 2004 and as required by Appellant's claims. Vitamin C disclosed as an unprotected antioxidant by SS Pharmaceutical, Tsunoda and Yeh et al continually oxidizes and decreases to unknown amount(s) having unknown properties that are not intended to supplement nutrition and cannot be indicated. So, they do not disclose vitamin C formulated as a nutritional supplement because it cannot be indicated by an amount and percent daily value and it is not intended to supplement nutrition. And, vitamin C formulated as an unprotected antioxidant is not a nutritional supplement regardless of its intended use as an antioxidant. Also, it is not useful by Appellant's claimed invention, because it not stable and cannot be predetermined or indicated as an amount or percent daily value. There is no teaching in the applied prior art to suggest the combination, so it is improper. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, indicating vitamin C formulated as a

nutritional supplement, by its amount and percent daily value in a unit dose of discomfort reliever is not obvious from the applied prior art, as required by Appellant's claims. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

AN AMOUNT FUNCTIONS IN RELATIONSHIP TO LABELING THAT AMOUNT

The Examiner states that the step of labeling is printing and is not structural, functional or operational for the ingredients (citing Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987) and In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir, 1990), Examiner's Answer, pages 5-7, 11, 12, 14 and 16-25. But, labeling functions to indicate an amount and percent daily value of vitamin C, which is required for it to be a nutritional supplement, 21 CFR 101.36 Exhibit D, of the Amendment filed May 19, 2004. Printed matter may well constitute limitations upon which patentability can be predicated, In re Lowry, 32 F3d 1579, 32 USPQ2d 1031, 1034 (Fed Cir 1994). And, to indicate (label) an amount of vitamin C that amount must be stable, so that it remains as indicated, as required for it to be a nutritional supplement by 21 CFR 101.36 Exhibit D, of the Amendment filed May 19, 2004 and Appellant's claims. The characterization of printed matter as unpatentable is beside the point, because no attempt is here being made to patent printed matter as such, In re Miller 164 USPQ 46, 49 (CCPA, 1969). The fact that printed matter is not patentable subject matter *by itself* is no reason for ignoring it when the claim is directed to a combination, In re Miller, 49. Indications indicating an amount of vitamin C in a unit dose of discomfort reliever constitute limitations not disclosed by the prior art, and they have unexpectedly superior results, upon which patentability can be predicated, In re Lowry. Standing alone the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art In re Lowry. The Court in Miller found that printed matter of an invention was functionally related to volume measuring and reversed the rejection, In re Gulack 703 F2d at 1385, 217 USPQ 401, 404 (CAFC, 1983).

An amount of vitamin C must be stable to be indicated. For vitamin C to be nutritional supplement in a unit dose of a discomfort reliever, its amount must be stable and indications indicating its amount and percent daily value are required by 21 CFR 101.36. This stable amount and indications indicating it are limitations of the claims, which are not disclosed by the applied prior art. Each element of a claim is material and essential, Perkin – Elmer Corp. An element substituted for an element in a claim must not be such as would substantially change the way in which the function of the invention is performed, Perkin – Elmer Corp at 1325. A vitamin C formulation, as an element substituted for an element in a claim, must not be such as would substantially change the way in which the function of the invention is performed, Perkin – Elmer Corp at 1325.

Vitamin C formulated without protection from oxidation as an antioxidant in SS Pharmaceutical, Tsunoda and Yeh et does not function the same as vitamin C formulated as a stable nutritional supplement required by the invention. As an antioxidant without oxidation protection, vitamin C is destroyed by oxidization. And, it is not known how much vitamin C and its nutrition-supplementing property and its nutrition-supplementing function remain. So it cannot be predetermined or indicated, as required to be a nutritional supplement by 21 CFR 101.36 and Appellant's claims. While as a nutritional supplement, an amount of vitamin C is stable so it can be predetermined and indicated. And, that stable amount of vitamin C represents a corresponding nutrition-supplementing property and its nutrition-supplementing function. Substituting the vitamin C formulated without oxidation protection as an antioxidant of SS Pharmaceutical, Tsunoda and Yeh et, for vitamin C formulated as a stable nutritional supplement of the invention, substantially changes (completely obliterates) the way in which the indicating function of the invention would be performed, so it cannot be performed. So, the rejection is improper, Perkin – Elmer Corp.

A scientific explanation for the differences between the properties of the invention and the references may be needed to correctly apply or understand the references, In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir, 1990). The differences between the properties of the invention and the references result

from vitamin C being destroyed by oxidation in its formulation without oxidation protection as an antioxidant of SS Pharmaceutical, Tsunoda and Yeh et al. While vitamin C is not destroyed by oxidation in its formulation as a stable amount of a nutritional supplement of the invention. Vitamin C must be formulated to prevent its oxidization to be stable as an amount of a nutritional supplement. But, vitamin C continually decreases in amount due to oxidation when it is formulated as an antioxidant without protection from oxidation. So, its amount is not known and cannot be indicated in SS Pharmaceutical, Tsunoda and Yeh et al, as discussed above. A scientific explanation for these differences is that they formulate vitamin C differently.

For example, the material formulated to supplement nutrition may be dried to contain 4 percent or less of moisture, and contain complexing agents, Fuckamachi et al US Patent 4,929,774 Abstract, column 2, lines 1-7 and Examples 1-6, columns 4-8: APPENDIX C. To formulate a vitamin for supplementing nutrition, antioxidants may be added, as disclosed at column 12, lines 53-57 of Hermelin et al US Patent 6,576,666 APPENDIX D. Neither, SS Pharmaceutical, Tsunoda nor Yeh et al discloses antioxidants to maintain the amount of vitamin C. They do not disclose drying, moisture content, complexing agents or supplementing nutrition. And, they do not disclose an amount or a percent daily value of vitamin C that can be indicated.

Indications indicate (label) a quantitative amount and percent daily value of a nutritional supplement, 21 CFR 101.36 Exhibit D, of the Amendment filed May 19, 2004. Indicating an amount of vitamin C requires it to be maintained, so that it can be indicated, as required to be a nutritional supplement, 21 CFR 101.36. Indications indicating an amount or percent daily value of vitamin C in a unit dose of discomfort reliever constitute limitations of Appellant's claims that are not disclosed by the prior art. And these limitations have unexpectedly superior results of reducing by half the number of containers and compositions required by the prior art. So, patentability can be predicated on them, In re Lowry, 32 F3d 1579, 32 USPQ2d 1031 (Fed Cir 1994). The PTO must consider all claim limitations, when determining patentability of an invention over the prior art. In re

Gulack 1385. The PTO may not disregard claim limitations comprised of printed matter, In re Gulack 1384 and Diamond v Diehr 450 US 175, 191 209 USPQ 1 (1981). Substituting vitamin C formulated without oxidation protection as an antioxidant of SS Pharmaceutical, Tsunoda and Yeh et al for vitamin C formulated as a stable nutritional supplement of the invention, substantially changes the way in which the function of the invention would be performed, so that it cannot be performed. Thus, the rejection is improper, Perkin – Elmer Corp. They do not disclose a predetermined amount of vitamin C that can be indicated, as required to be a nutritional supplement by 21 CFR 101.36 and as required by Appellant's claims. And, they are not properly combined with Krause, as discussed above. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, indicating an amount and percent daily value of nutritional supplement in a unit dose of discomfort reliever is not obvious from the applied prior art, as required by Appellant's claims. Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

LABELING DECREASING AMOUNT IS NOT CONVENTIONAL OR POSSIBLE

The Examiner states that labeling is of no patentable weight, since the ingredient properties are inherent and inseparable from their function, and that labeling a container is conventional, citing In re Miller 164 USPQ 46 (CCPA, 1969) and In re Gulack 217 USPQ 401 (CAFC, 1983) Examiner's Answer, pages 5-7, 11, 12, 14 and 16-25. And, he states that it would be obvious to indicate the amount of vitamin C, at page 4 of the Examiner's Answer. But, unknown amounts of vitamin C oxidizing as antioxidants having unknown nutrition-supplementing properties cannot be indicated or labeled by their unknown amount(s) in products based on SS Pharmaceutical, Tsunoda and Yeh et al. So, labeling is of patentable weight, to indicate a stable amount of vitamin C in a unit dose of discomfort reliever. Since when vitamin C is formulated without oxidation protection as an antioxidant its amount and its properties and their inherent and

inseparable nutrition-supplementing function are unknown and cannot be indicated. So, labeling a container to indicate oxidizing, decreasing unknown amount(s) of vitamin C formulated as an antioxidant in a unit dose of discomfort reliever is not conventional, obvious or possible.

Vitamin C is easily destroyed by oxidation, Parker, Encyclopedia of Science and Technology, Antioxidant: page 124: APPENDIX B and Lieberman and Bruning, The Real Vitamin & Mineral Book, page 126, 1997 Appeal Brief, APPENDIX B. Vitamin C destroyed by oxidation does not function as vitamin C, and is not a nutritional supplement. So, an amount of vitamin C must be protected from oxidation to be maintained and indicated as a nutritional supplement, as required by 21 CFR 101.36(b), and as claimed by Appellant. SS Pharmaceutical, Tsunoda and Yeh et al disclose vitamin C without protection from oxidation, so it oxidizes and decreases unpredictably to unknown amount(s) that cannot be indicated.

Thus, vitamin C and its properties and their inherent and inseparable functions are easily destroyed by its oxidation. As vitamin C is oxidized its amount, and its properties and their inherent and inseparable functions decrease unpredictably to unknown amount(s), having unknown properties and unknown functions. Formulating vitamin C to prevent its oxidization in a unit dose of a discomfort reliever protects its amount and its properties and their inherent and inseparable functions, so they can be indicated by that amount and its percent daily value, as is required to be a nutritional supplement and Appellant's claims. Thus, the nutrition-supplementing function and the properties of vitamin C are inherent and inseparable from its amount. Indicating that amount is a new function for a unit dose of discomfort reliever in Appellant's claimed invention. And, labeling oxidizing, decreasing unknown amount(s) of vitamin C is not conventional, obvious or possible in products based on SS Pharmaceutical, Tsunoda and Yeh et al.

The Court in Miller found that the printed matter was functionally related to volume measuring and reversed the rejection, In re Gulack. Similarly, the function of indicating an amount of vitamin C is related to that amount being

formulated to prevent its oxidation to maintain its amount and its nutrition-supplementing function and properties. This indicating function is comparable to that of indicia and legends on the receptacle specifying a functional relationship in In re Miller 164 USPQ 46, 48 (CCPA, 1969). So, there is a new functional relationship between an amount of a nutritional supplement, and an indication (label) indicating it for a unit dose of discomfort reliever in Appellant's claimed invention. Also, there is a new functional relationship between the percent of a daily value of a nutritional supplement, and an indication (label) indicating it for a unit dose of discomfort reliever in Appellant's claimed invention. Thus, these new indicating functions for vitamin C in unit dose of a discomfort reliever are of patentable weight. Since the new stability of its amount maintains its properties and their inherent and inseparable nutrition- supplementing functions. So, they can be indicated by a predetermined amount and a percent daily value of vitamin C, In re Gulack.

SS Pharmaceutical, Tsunoda and Yeh et al disclose vitamin C formulated without oxidation protection as an antioxidant. So it is oxidized and decreases to unknown amount(s) and percent daily value(s) that cannot be indicated. By contrast, there is a new functional relationship between a stable amount and percent daily value of vitamin C in a unit dose of discomfort reliever and indications on its enclosure indicating them, as required to be a nutritional supplement, 21 CFR 101.36 and as claimed by Appellant. This is of patentable weight, since an amount and percent daily value of vitamin C are unknown, so labeling them is not conventional, obvious or possible in products based on SS Pharmaceutical, Tsunoda and Yeh et al, In re Gulack. And, labeling a decreasing unknown amount of vitamin C is not conventional, obvious or possible. Also, they are not properly combined with Krause, as discussed above. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, indicating an amount and percent daily value of nutritional supplement in a unit dose of discomfort reliever is not obvious from the applied prior art, as required by Appellant's claims. Accordingly, the rejection of

Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

NUTRITIONAL SUPPLEMENT DOES NOT FUNCTION THE SAME WITHOUT A LABEL

The Examiner states that the ingredients function the same without a label, and that there is no functional relationship between the ingredients and the label, Examiner's Answer, pages 5-7, 11, 12, 14 and 16-25. But, vitamin C does not function as a nutritional supplement without a label to indicate its name, amount and percent daily value to the consumer. Without these indications the consumer would not know to consume it as a nutritional supplement of its unidentified amount and unknown nutrition-supplementing function. So, there is a functional relationship between a stable amount of vitamin C and its label indicating that amount. However, vitamin C formulated as an unprotected antioxidant does not function the same as vitamin C formulated as a stable amount of nutritional supplement. It oxidizes to unknown amount(s) that cannot be indicated. SS Pharmaceutical, Tsunoda and Yeh et al disclose vitamin C formulated without oxidation protection as an antioxidant. Thus, an amount of vitamin C cannot be indicated on their labels since it is not known.

Oxidized vitamin C does not have the properties or functions of vitamin C. And, oxidized vitamin C cannot be indicated as vitamin C or as a nutritional supplement. So, vitamin C is continually oxidized and decreases to unknown amount(s) in products based on SS Pharmaceutical, Tsunoda and Yeh et al, because it is not formulated to be protected from oxidation, as discussed above. Vitamin C decreasing in amount is not a nutritional supplement, because its amount is not known so it cannot be indicated. Thus, SS Pharmaceutical, Tsunoda and Yeh et al do not disclose formulating vitamin C to be protected from oxidation so its amount is maintained and can be indicated, as required for nutritional supplements by 21 CFR 101.36(b) and Appellant's claims.

A nutritional supplement formulation has a quantitative amount and a percent daily value of a vitamin, which must be indicated on a label, 21

CFR101.36(b)(ii)(A) and 21 CFR101.36(b)(iii): Exhibit D, of the Amendment filed May 19, 2004 and 21 CFR 211.137(a): APPENDIX A. Thus, indications indicating an amount (and percent daily value) of vitamin C are related to that amount of vitamin C being formulated to be protected from oxidation so it is maintained and can be indicated. Neither indicating an amount of vitamin C nor protecting vitamin C from oxidation in a unit dose of discomfort reliever are disclosed by the applied prior art. And, they have unexpectedly superior results, of reducing by half the number of compositions and containers required for the same discomfort relieving and nutrition supplementing functions. So they are matter that constitute limitations upon which patentability can be predicated, In re Lowry, 32 F3d 1579, 32 USPQ2d 1031, 1034 (Fed Cir 1994).

Thus, the function of indicating vitamin C on a label is related to protecting it from oxidation to maintain its amount, so it can be labeled. An amount of vitamin C is not maintained, so an amount cannot be labeled in SS Pharmaceutical, Tsunoda and Yeh et al. So, their formulations of vitamin C as unprotected antioxidants do not function the same as formulations of vitamin C as a nutritional supplement required by Appellant's invention. They disclose vitamin C formulated as an unprotected antioxidant, so it is oxidized and decreases to unknown amount(s) that cannot be indicated as an amount and percent daily value. And, indicating a quantitative amount and percent daily value of vitamin C, is required for it to be a nutritional supplement, as required by Appellant's claims and 21 CFR101.36(b)(ii)(A) and 21 CFR101.36(b)(iii): Exhibit D, of the Amendment filed May 19, 2004 and 21 CFR 211.137(a): APPENDIX A. The new function of indicating an amount and percent daily value of vitamin C is related to preventing its oxidation to maintain its amount and percent daily value in a unit dose of discomfort reliever. The indicating function indicates a stable amount and percent daily value of vitamin C to let the consumer know whether a sufficient amount and percent daily value are being consumed.

Printed matter may well constitute limitations upon which patentability can be predicated, In re Lowry, 32 F3d 1579, 32 USPQ2d 1031, 1034 (Fed Cir 1994). The Court in Gulack cautioned against liberal use of printed matter rejections

under section 103. A printed matter rejection under section 103 stands on questionable legal and logical footing. Standing alone the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art, In re Lowry.

And, the new function of indicating an amount and percent daily value of vitamin C is related to protecting vitamin C from oxidation so that it is maintained as a quantitative amount of nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever. Indicating a quantitative amount of vitamin C in a unit dose of discomfort reliever is not disclosed by the prior art. It is taught away from by SS Pharmaceutical, Tsunoda and Yeh et al by their disclosure of vitamin C formulated without oxidation protection as an antioxidant. And it has unexpectedly superior results of reducing by half the number of compositions and containers that are required by the prior art. So, it is matter that constitutes limitations upon which patentability can be predicated, In re Lowry. And, the applied prior art references do not teach or suggest their combination, so the rejection is improper, as discussed above. So, it is not obvious from the applied prior art to formulate vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims. And, indicating a quantitative amount and percent daily value of nutritional supplement in a unit dose of discomfort reliever is not obvious from the applied prior art, as required by Appellant's claims. Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

FORMULATIONS TO DECREASE OR TO BE MAINTAINED ARE NOT IDENTICAL

The Examiner notes that if the prior art teaches identical chemical structure, the properties are the same (Examiner's Answer page 6). But, the prior art does not teach an identical chemical structure, or the same properties, that are required by Appellant's claims. SS Pharmaceutical, Tsunoda and Yeh et al teach vitamin C unprotected as an antioxidant to form oxidized vitamin C. Vitamin C destroyed by

oxidation does not have an identical chemical structure to vitamin C. And, vitamin C destroyed by oxidation does not have the same properties as vitamin C.

SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation and intended to be oxidized. So, vitamin C is oxidized unpredictably to unknown amounts that cannot be predetermined or indicated in products based on them. And, oxidized vitamin C is not chemically identical to vitamin C. Its properties are not the same as vitamin C. And, its functions are not the same as vitamin C. SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose indicating supplementing nutrition or any intention of supplementing nutrition. They do not disclose a percent daily value for vitamin C. They do not disclose indicating an amount of vitamin C or indicating a percent daily value for vitamin C. They do not disclose a vitamin C formulated as a nutritional supplement, an amount of vitamin C that can be indicated, or vitamin C formulated as used by Appellant's claimed invention.

Thus, vitamin C destroyed by oxidation does not have an identical chemical structure or identical properties to vitamin C. Vitamin C formulated without oxidation protection as an antioxidant, is continually destroyed by oxidation in products based on SS Pharmaceutical, Tsunoda and Yeh et al. It oxidizes and decreases to unknown amount(s) having unknown properties that cannot be indicated. Vitamin C is easily destroyed by oxidation, Parker, Encyclopedia of Science and Technology, Antioxidant: page 124: APPENDIX B and Lieberman and Bruning, The Real Vitamin & Mineral Book, page 126, 1997 Appeal Brief, APPENDIX B. While, vitamin C formulated as a nutritional supplement maintains an amount that is indicated. So, formulations of vitamin C oxidizing and decreasing in amount cannot be chemically identical to those with a stable amount of vitamin C. Thus, these formulations do not have the same properties regarding whether or not vitamin C oxidizes and decreases.

For example, the material formulated to supplement nutrition disclosed by Fuckamachi et al US Patent 4,929,774 (APPENDIX C) is dried to contain 4 percent or less of moisture, and contains complexing agents, (Abstract, column 2, lines 1-7 and Examples 1-6, columns 4-8). To formulate a vitamin for supplementing nutrition,

antioxidants may be added, as disclosed at column 12, lines 53-57 of Hermelin et al US Patent 6,576,666: APPENDIX D. Neither SS Pharmaceutical, Tsunoda nor Yeh et al disclose antioxidants to maintain the amount of vitamin C, drying, moisture content, or supplementing nutrition. Some of the antioxidant compositions of Yeh et al are more than half water (Examples 3 and 5).

Indicating a predetermined amount and percent daily value of vitamin C is required by Appellant's claims. An amount and percent daily value of vitamin C cannot be indicated in SS Pharmaceutical, Tsunoda and Yeh et al because they disclose vitamin C formulated without oxidation protection as an antioxidant, so it decreases to unknown amount(s) and unknown percent daily value(s) having unknown properties that cannot be indicated. Their formulations do not protect a quantitative amount of vitamin C from oxidation. So, in their formulations vitamin C is destroyed by oxidation, and it no longer has an identical chemical structure to vitamin C. And, vitamin C destroyed by oxidation does not have the same properties as vitamin C. Their formulations of vitamin C are not nutritional supplements. A quantitative amount and percent daily value must be indicated, to be a nutritional supplement as required by 21 CFR 101.36 and Appellant's claims. So, SS Pharmaceutical, Tsunoda and Yeh et al do not teach a chemical formulation, or properties, that are an identical to or the same as the nutritional supplement required by Appellant's claims. And, the applied prior art references do not teach or suggest their combination. So, formulating vitamin C as a nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims, is not obvious from the applied prior art. And, indicating an amount and a percent daily value of nutritional supplement in a unit dose of discomfort reliever, as required by Appellant's claims, is not obvious from the applied prior art. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

BOTH RELIEF OF DISCOMFORT AND SUPPLEMENTING NUTRITION ARE REQUIRED BY APPELLANT'S INVENTION

The Examiner states that the claims are directed to a method of indication comprising enclosing discomfort reliever and nutritional supplement and specific indications thereof, Examiner's Answer, page 3. Indicating predetermined amounts of both the nutritional supplement and the discomfort reliever is required by Appellant's claims. Indicating a percent of a daily value for a predetermined amount of nutritional supplement in a unit dose of discomfort reliever is required by Appellant's claims. Indications indicating a nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever are required by Appellant's claims. And, a method for relief of discomfort and supplementing nutrition is required by Appellant's claims. None of these limitations of the claims is disclosed by the prior art.

SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C without protection from oxidation. So it is continually oxidized and decreases to unknown amount(s). Thus, they cannot indicate an amount of vitamin C, or a percent daily value for an amount of vitamin C, as required by Appellant's claims, as discussed above. Indicating predetermined amounts of both the nutritional supplement and the discomfort reliever is required by Appellant's claims. Indicating a percent of a daily value for a predetermined amount of nutritional supplement in a unit dose of discomfort reliever is required by Appellant's claims. Indications indicating a nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever are required by Appellant's claims. None of the applied prior art references discloses these features. And, by disclosing vitamin C formulated as an antioxidant without protection from oxidation, they teach away from its formulation as a nutritional supplement , as required by Appellant's claims. And away from indicating a predetermined amount of it, as required by Appellant's claims. And, they are not properly combined with Krause, as discussed above.

Where words of the preamble are necessary to give meaning to the claim and properly define the invention they are deemed limitations of the claim,

Gerber Garment Technology Inc v Lectra Systems Inc, 916 Fd2 683, 16 USPQ2d 1436, 1441 (Fed Cir 1990) and Perkin-Elmer Corp v Computervision Corp 732 F2d 888, 896, 221 USPQ 669, 675 (Fed Cir 1984). A method for relief of discomfort and supplementing nutrition is required by Appellant's claims. None of the applied prior art references discloses this feature. And, they are not properly combined with Krause, as discussed above.

The Court has stressed the importance of each element in the claim, Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S. Ct. 1040, 1049 (1997). Each element of a claim is material and essential, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Appellant's claims require a method for relief of discomfort and supplementing nutrition. They require indicating a predetermined amount of nutritional supplement in a unit dose of discomfort reliever. They require indicating a percent of a daily value for the predetermined amount of nutritional supplement in a unit dose of discomfort reliever. And, they require indicating a nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever. These limitations of the claims are not disclosed by the applied prior art. The PTO must consider all claim limitations, when determining patentability of an invention over the prior art. In re Gulack 703 F2d at 1385, 217 USPQ 401, 403 (CAFC, 1983). Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

SUPERIOR RESULTS

The Examiner states that there is no data presented to evaluate whether superior results are presented, and that unexpected beneficial results must be clear and convincing and be demonstrated by statistical and practical significance, citing Ex parte Gelles 22 USPQ2d 318, 319 (Bd. Pat. App. & Inter.1992), In re Lohr 137 USPQ 548 (CCPA,1963) and In re Linder 173 USPQ 356 (CCPA, 1972), MPEP 716.02 and 716.02(a)-(g), Examiner's Answer pages 10 and 21. But, disclosure in the specification of data clearly and convincingly demonstrating by statistical and

practical significance superior results must be considered, In re Soni 54 F3d 746, 749, 34 USPQ2d 1684, 1687 (Fed Cir 1995). Appellant's original specification disclosure discloses the invention as reducing by half the number of unit doses and by half the number of containers, pages 1, 12 and 32-34. This is data clearly and convincingly demonstrating superior results of statistical and practical significance, Ex parte Gelles; In re Lohr and In re Linder. Given the similar compositions of SS Pharmaceutical, Tsunoda and Yeh et al to those useful in Appellant's invention, the substantially improved results of Appellant's invention are *ipso facto* unexpected, In re Soni.

Appellant's invention has unexpectedly superior results of requiring only half as many unit dose compositions and half as many containers and half as much storage space compared to the distinctively labeled, separately enclosed discomfort reliever products and nutritional supplement products of the prior art. The consumer saves the time and expense that would otherwise be needed to purchase twice as many containers of the distinctively labeled, separately enclosed discomfort reliever products and nutritional supplement products of the prior art. And, it adds the convenience of consuming only half as many unit dose compositions compared to the separate discomfort reliever products and nutritional supplement products of the prior art. Use of Appellant's invention enables the user to self-regulate consumption of nutritional supplements while alleviating a discomfort.

There has been a long felt need for regular consumption of nutritional supplements, COUNCIL FOR RESPONSIBLE NUTRITION, The Benefits of Nutritional Supplements, Executive summary 2001 (see page 1, last paragraph of the above captioned patent application). For consumers who regularly consume a discomfort reliever, by use of Appellant's invention they also regularly consume nutritional supplements (Appeal Brief pages 10-11). They have improved ability to self-regulate consumption of nutritional supplements, over the prior art. The nutritional supplement products of the prior art are separate from discomfort reliever products. And regularly consuming them requires regularly remembering the need to consume them, as well as finding, opening and closing twice as many containers and consuming twice as many doses as Appellant's invention. It is a practically

significant benefit of the invention compared to the applied prior art, that the user consumes one dose of discomfort reliever and knows from indications on its enclosure an amount and a percent daily value for a nutritional supplement consumed. It results in improved regularity in supplementing nutrition, superior convenience and superior savings in unit dose compositions, containers, and storage capacity. The statute does not require a patentable invention to be superior Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988). Thus, patentability is shown beyond the requirements of the statute, Demaco. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

IT IS IMPROPER TO DISREGARD THE SPECIFIC NATURE OF THE MATERIAL RESPONSIBLE FOR THE UNOBVIOUS RESULT

It is not proper to disregard the specific nature of the material employed in the claimed process which is responsible for the unobvious result. If the result of the process is unobvious and the particular use of the material is not suggested by the prior art the process claimed should be allowed, Ex Parte Wagner 88 USPQ 217, 220 (Pat. Off. Bd. App., 1950). The superior results of the claimed method are unobvious (Appeal Brief, pages 11-13), and the use of the vitamin C formulated to be maintained in amount for supplementing nutrition in a unit dose of ibuprofen is not suggested by the prior art, (Appeal Brief, pages 2-5 and 13-18). So, the method claimed should be allowed, Ex Parte Wagner. Given the similar compositions of SS Pharmaceutical, Tsunoda and Yeh et al to those useful in Appellant's invention, the substantially improved results of Appellant's invention are *ipso facto* unexpected, 54 F3d 746, 749, 34 USPQ2d 1684, 1687 (Fed Cir 1995). So the method claimed should be allowed, Ex Parte Wagner. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

COMPARATIVE DATA OF UNEXPECTED RESULTS MUST BE CONSIDERED

The PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results, In re Soni, 54 F3d 746,

751, 34 USPQ2d 1684, 1688 (Fed Cir 1995). Where Applicant's specification contains more than mere argument, and contains specific data indicating superior results it must be considered, In re Soni. Appellant's original specification contains more than mere argument. It contains specific data comparing the reduction of containers and unit doses by half compared to the prior art, which indicates superior results, pages 1, 12 and 32-34. So, the PTO must consider this comparative data in the specification in determining whether the claimed invention provides unexpected results, In re Soni.

The substantially improved superior results of the claimed method are unexpected (Appeal Brief, pages 11-13). These results include the same discomfort relief with improved ability to self-regulate consumption of nutritional supplements, while opening and closing half as many containers, and consuming half as many unit dose compositions compared to the separate discomfort reliever products and nutritional supplement products of the prior art, (The original specification pages 1, 12 and 32-34 and Appeal Brief, pages 11-13).

Given a presumption of similar properties for similar compositions, substantially improved results are *ipso facto* unexpected, In re Soni 54 F3d at 750, 34 USPQ2d at 1688. So, given the similar compositions of SS Pharmaceutical, Tsunoda and Yeh et al to those useful in Appellant's invention, the substantially improved results of Appellant's invention are *ipso facto* unexpected, In re Soni. There is simplicity of the new invention, given the similar compositions of SS Pharmaceutical, Tsunoda and Yeh et al to those useful in Appellant's invention. But, the simplicity of the new invention is often the very thing that is not obvious before it is made, In re Sporck 301 F2d 686, 133 USPQ 360 (CCPA, 1962). Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

OMISSION OF AN ELEMENT WITH RETENTION OF THE ELEMENT'S FUNCTION IS AN INDICIA OF UNOBVIOUSNESS

Omission of an element with retention of the element's function is an indicia of unobviousness, In re Edge, 359 F2d 896, 149 USPQ 556 (CCPA,

1966). Appellant's invention has indicia of unobviousness, since, it omits half of the number of unit dose compositions and half of the number of containers required by the prior art with retention of all of their functions, In re Edge.

Prior art discomfort reliever products and nutritional supplement products are disclosed, regulated and sold separately, as discussed in the Appeal Brief at pages 6 and 7. They are sold as separate and distinct products having distinctively labeled separate containers, such as those disclosed in the above captioned patent application at pages 29-31; EXHIBITS A-G of the Amendment filed March 1, 2004; and Exhibit B of the Amendment filed May 19, 2004.

One of the nutritional supplement consumer's problems is routinely remembering to find and consume the nutritional supplement. For consumers of nutritional supplement and discomfort reliever, twice as many containers and more storage capacity is needed to contain and store the separate unit doses of pain reliever (such as Advil) and nutritional supplement (such as Centrum), than are required by Appellant's invention.

Appellant's invention omits half of the number of unit dose compositions and half of the number of containers of the separate pain reliever products and nutritional supplement products of the prior art, while the functions of both products are retained in one product, (Appeal Brief, page 13). Omission of an element with retention of the element's function is an indicia of unobviousness, In re Edge, 359 F2d 896, 149 USPQ 556 (CCPA, 1966), and MPEP 2144.04, II, B. So, Appellant's invention has indicia of unobviousness, since, it omits half of the number of unit dose compositions and half of the number of containers required by the prior art with retention of all of their functions, In re Edge. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

TO READ THE CLAIM INDISCRIMINATELY TO COVER ALL TYPES OF COMPOSITIONS AND DEVICES WOULD BE DIVORCED FROM REALITY

The Court has stressed the importance of each element in the claim, Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S. Ct. 1040, 1049 (1997).

Enclosing a predetermined amount of nutritional supplement in a unit dose of discomfort reliever are elements of Appellant's claimed invention, which are not disclosed in the applied prior art. Indicating a predetermined amount of nutritional supplement in a unit dose of discomfort reliever are elements of Appellant's claimed invention, which are not disclosed in the applied prior art. And, indicating a percent daily value for a predetermined amount of nutritional supplement in a unit dose of discomfort reliever are elements of Appellant's claimed invention, which are not disclosed in the applied prior art. To read the claim in light of the specification indiscriminately to cover all types of compositions and devices would be divorced from reality, Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1255-57, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989).

To function as a nutritional supplement useful in the invention, vitamin C must be formulated so that an amount can be predetermined and indicated, as defined by the specification, Corning 1966. SS Pharmaceutical, Tsunoda, and Yeh et al, disclose vitamin C formulated without oxidation protection as an antioxidant with ibuprofen anti-inflammatory to synergistically reduce pain or inflammation. So, its amount decreases as it is oxidized to unknown amounts that cannot be predetermined or indicated as an amount or percent daily value, as required by Appellant's claims, and 21 CFR 101.36. The combination of applied prior art references requires a reading of the claim in light of the specification that indiscriminately covers all types of compositions and devices, so it is divorced from reality, Corning Glass Works. The applied prior art erroneously omits elements in the claim by not disclosing a nutritional supplement in a unit dose of discomfort reliever that can be indicated as an amount or percent daily value, Warner-Jenkinson Co. It erroneously omits elements in the claim by not disclosing indicating a predetermined amount of nutritional supplement in a unit dose of discomfort reliever, Warner-Jenkinson Co. It erroneously omits elements in the claim by not disclosing indicating a percent daily value for a nutritional supplement in a unit dose of discomfort reliever, Warner-Jenkinson Co. Also, the applied prior art references do not teach or suggest the combination, so it is improper, as discussed above.

Accordingly, the rejection of Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda and Yeh et al in view of Krause is erroneous.

CLAIMED FEATURES NOT DISCLOSED CANNOT BE MEANINGFULLY CONSIDERED, MAKING THE REJECTION IMPROPER

The court has held that the absence from the applied references of an explicit requirement of the claims makes the rejection improper, In re Evanega 4 USPQ 2nd 1249 (CAFC, 1987). And, all of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Enclosing and indicating a predetermined amount of nutritional supplement in a method for discomfort relief and supplementing nutrition are absent from the applied prior art and are explicitly required in Claims 48, 50-54, 56, 59-61, 64-69, and 71-81. Neither, SS Pharmaceutical, Tsunoda, Yeh et al nor Krause discloses these features. And they are not properly combined, as discussed below. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of these explicit requirements of the claims makes the rejection improper, In re Evanega. Accordingly, the rejection of claims 48, 50-54, 56, 59-61, 64-69, and 71-81 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper, (Appeal Brief at pages 17 and 18).

Indications indicating a percent daily value for a nutritional supplement in a method for discomfort relief and supplementing nutrition, are absent from the applied prior art, and are explicitly required by Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94. And, indicating a predetermined amount of the nutritional supplement in a method for discomfort relief and supplementing nutrition are absent from the applied prior art, and are explicitly required by Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94. Neither, SS Pharmaceutical, Tsunoda, Yeh et al nor Krause discloses these features. And they are not properly combined, as discussed below. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of these explicit requirements of the claims makes the rejection improper, In re Evanega. Accordingly, the rejection

of claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper (Appeal Brief at pages 17 and 18).

Indications indicating from one to fifty percent daily value of a nutritional supplement in a unit dose of discomfort reliever are absent from the applied prior art, and are explicitly required by Claims 33, 86 and 94. Indicating a predetermined amount of the nutritional supplement in a method for discomfort relief and supplementing nutrition, are absent from the applied prior art, and are explicitly required by Claims 33, 86 and 94. SS Pharmaceutical, Tsunoda, and Yeh et al and Krause do not disclose these features. And they are not properly combined, as discussed above. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of these explicit requirement of the claims makes the rejection improper, In re Evanega. Accordingly, the rejection of claims 33, 86 and 94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper(Appeal Brief at pages 17 and 19).

Indications indicating instructions for consuming a unit dose of discomfort reliever for supplementing nutrition are absent from the applied prior art, and are explicitly required by Claim 79. And, indicating a predetermined amount of nutritional supplement in a method for discomfort relief and supplementing nutrition are absent from the applied prior art, and are explicitly required by Claim 79. Neither, SS Pharmaceutical, Tsunoda, Yeh et al nor Krause discloses these features. And, they are not properly combined, as discussed below. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. And, the absence from all of the applied references of these explicit requirements of the claim makes the rejection improper, In re Evanega. Accordingly, the rejection of claim 79 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause, is erroneous and improper (Appeal Brief at pages 18).

A REFERENCE TEACHES AWAY, IF IT IS UNLIKELY TO BE PRODUCTIVE OF THE RESULT SOUGHT

In general a reference will teach away, if it suggests that the line of

development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant, In re Gurley 27 F3d 551; 31 USPQ 2d 1130, 1132 (CAFC, 1994). By disclosing vitamin C formulated without protection from oxidation as an antioxidant, SS Pharmaceutical, Tsunoda and Yeh et al teach away from formulating it as a nutritional supplement and away from indicating a predetermined amount of it in a unit dose of a discomfort, as required by Appellant's claims. The result sought by claims 48, 50-54, 56, 59-61, 64-69, and 71-81 include indicating supplementing nutrition for a predetermined amount of nutritional supplement in a unit dose of a discomfort reliever. None the applied prior art references discloses these results, SS Pharmaceutical, Tsunoda and Yeh et al teach away from them, and they are not properly combined with Krause, as discussed above. So, they are unlikely to produce the result, In re Gurley. Accordingly, the rejection of claims 48, 50-54, 56, 59-61, 64-69, and 71-81 as obvious over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

By disclosing vitamin C formulated without protection from oxidation as an antioxidant, SS Pharmaceutical, Tsunoda and Yeh et al teach away from formulating it as a nutritional supplement, as required by Appellant's claims. They teach away from indicating a percent daily value, as required by Appellant's claims. And they teach away from indicating a predetermined amount of nutritional supplement, as required by Appellant's claims. Indicating a percent daily value, and indicating a predetermined amount of nutritional supplement in a unit dose of a discomfort reliever is a result sought in Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94. None the applied prior art references disclose these results, SS Pharmaceutical, Tsunoda and Yeh et al teach away from them, and they are not properly combined with Krause, as discussed above. So, they are unlikely to produce the result, In re Gurley. Accordingly, Claims 26-30, 33-35, 37-46, 82-84, 86-87 and 91-94 are not prima facie obvious over the combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause.

By disclosing vitamin C formulated without protection from oxidation as an antioxidant, SS Pharmaceutical, Tsunoda and Yeh et al teach away from formulating it as a nutritional supplement, as required by Appellant's claims. They teach away

from indicating a percent daily value, as required by Appellant's claims. And they teach away from indicating a predetermined amount of nutritional supplement, as required by Appellant's claims. Indicating from one to fifty percent daily value and indicating a predetermined amount of nutritional supplement in a unit dose of a discomfort reliever are results sought in Claims 33, 86 and 94. None the applied prior art references discloses these results, SS Pharmaceutical, Tsunoda and Yeh et al teach away from them, and they are not properly combined with Krause, as discussed above. So, they are unlikely to produce the result, In re Gurley. Accordingly, Claims 33, 86 and 94 are not prima facie obvious over the combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause.

By disclosing vitamin C formulated without protection from oxidation as an antioxidant, SS Pharmaceutical, Tsunoda and Yeh et al teach away from formulating it as a nutritional supplement, away from indicating a predetermined amount of nutritional supplement, and away from indicating supplementing nutrition, as required by Appellant's claims. Indicating instructions for consuming a unit dose of a discomfort reliever for supplementing nutrition, and indicating a predetermined amount of nutritional supplement in a unit dose of a discomfort reliever are results sought in claim 79. None the applied prior art references disclose these results, SS Pharmaceutical, Tsunoda and Yeh et al teach away from them, and they are not properly combined with Krause, as discussed above. So, they are unlikely to produce the result, In re Gurley. Accordingly, claim 79 is not prima facie obvious over the combination of SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause.

THE COMBINATION OF REFERENCES IS A HINDSIGHT RECONSTRUCTION

One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention, In re Fine, 837 F2d 1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). And, a proper combination of references cannot be based on forbidden hindsight, In re Rouffet 47 USPQ2d 1453, 1458 (CAFC, 1998). Disclosure of food labeling predetermined constant amounts of vitamin C formulated as nutritional supplements in Krause is isolated from disclosures of continually decreasing amounts of vitamin C that cannot be indicated in pain and/

anti-inflammatory medication of SS Pharmaceutical, Tsunoda, and Yeh et al. The rejection is erroneous because it relies upon hindsight reconstruction picking and choosing among disclosures of decreasing amounts in medication for pain and inflammation, and isolated disclosures of constant amounts in food labeling to depreciate the claimed invention. It is legal error to use the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). In constructing the rejection the Examiner combines SS Pharmaceutical, Tsunoda, Yeh et al and Krause without any teaching in the references for the combination thereof. The Examiner has made legally erroneous use of Appellant's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann. So, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause of the rejection is legal error.

The court has stated that a teaching is required in the references to suggest the combination thereof for a proper combination of references, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983). And, that the teaching or suggestion to make the claimed combination and a reasonable expectation of success must both be found in the prior art, not in Appellant's disclosure In re Vaeck 947 F 2d 488, 20 USPQ2d 1438 (Fed. Cir 1991). No teaching is provided by SS Pharmaceutical, Tsunoda, Yeh et al or Krause to suggest their combination, so the combination is improper (Appeal Brief pages 2-6). The prior art rejection is improper because it lacks both a teaching to make the claimed combination and a reasonable expectation of success.

And, it is erroneous to assume that labeling would include an indication indicating supplementing nutrition and percent daily value, which is neither disclosed in the applied prior art or prior commercial labeling, nor mandated by drug, food or dietary supplement labeling laws (Appeal Brief pages 21-34). And, it is erroneous to assert that it would be obvious to include indications indicating supplementing nutrition and percent daily value in a hypothetical drug label for a theoretical product, which is not intended to supplement nutrition. Thus, the rejection is unsupported, and inconsistent with the applied prior art, the law and prior commercial labeling of record.

So, it does not provide a reasonable expectation of success In re Vaeck.

The combination of references is not proper, because it is based on forbidden hindsight, In re Rouffet. None of the applied references discloses supplementing nutrition and relieving discomfort, as claimed by Appellant's claims. And, none of the applied references discloses enclosing and indicating predetermined amounts of nutritional supplement and discomfort reliever, as claimed by Appellant's claims. So, the reconstruction is insufficient as it omits these features of the invention, when it takes into account only knowledge, which was within the ordinary skill at the time of the invention. The reconstruction of the Final rejection is improper because it gleans this knowledge from Appellant's disclosure, In re McLaughlin 443 F2d 1392, 1395 170 USPQ 209, 212 (CCPA, 1971). All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Thus, the rejection does not meaningfully consider all of the limitations of the claims, Perkin – Elmer Corp. And, the combination of references is not proper, because it is based on forbidden hindsight, In re Rouffet. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

A METHOD OF INDICATING IS CLAIMED

Appellant's claims require a method for relief of discomfort and supplementing nutrition. Appellant's claims require indicating a predetermined amount of nutritional supplement in a unit dose of discomfort reliever. Appellant's claims require indicating a percent of a daily value for the predetermined amount of nutritional supplement in a unit dose of discomfort reliever. And, Appellant's claims require indicating supplementing nutrition for a nutritional supplement in a unit dose of discomfort reliever. These limitations of the claims are not disclosed by an applied prior art, as discussed in the Appeal Brief at pages 21-28. And, the applied prior art is not properly combined, as discussed above. The PTO must consider all claim limitations, when determining patentability of an invention over the prior art. In re Gulack 703 F2d at 1385, 217 USPQ 401, 403 (CAFC, 1983). And, even if formulations useful in the invention were known, the patent statute of 1952 recognizes (Sections 100(b) and

101) that the invention of a new use of a known composition or manufacture may be patentable as a method, In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as being unpatentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, and Yeh et al in view of Krause is erroneous.

RECONSIDERATION OF WITHDRAWAL FROM CONSIDERATION

The reconsideration of the Final Rejection respectfully requested, in the Amendment dated March 1, 2004 at page 22 is reiterated. Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 have been withdrawn from consideration as being drawn to non-elected species. Reconsideration of the withdrawal from consideration of these claims is respectfully requested. Each of Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 depends on a linking claim, which is generic thereto. If a linking claim is allowed, the Examiner must examine species linked thereto, [MPEP 809.04]. Accordingly, where the Examiner's reconsideration of the linking claims finds them to be patentable, withdrawal of the non-elected species should be considered. However, the Examiner is hereby again authorized to cancel Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 if needed for allowance of the above captioned patent application.

SUMMARY

A nutritional supplement in a unit dose of discomfort reliever is required by Appellant's claims. The claims require indications indicating an amount and percent daily value of the nutritional supplement in a unit dose of discomfort reliever. And, they also require indications indicating the nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever. These requirements are not disclosed, obvious, or possible from the applied prior art.

It is well know that vitamin C is easily destroyed by exposure to oxygen. SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation and intended to be oxidized. So, it is oxidized at unknown rates to unknown amounts of unknown nutrition-supplementing function. These unknown amounts cannot be predetermined or indicated as an amount and a percent daily value. Thus, indicating them is not conventional, obvious, or possible. But, an amount and a percent daily value must be indicated for a

nutritional supplement. So, SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose a nutritional supplement, within the scope of Krause, 21 USC 321 and 21 CFR 101.36 and Appellant's claims.

Unprotected antioxidant and stable nutritional supplement formulations of vitamin C are not chemically identical, and their nutrition-supplementing properties and functions are not the same. And, substituting the antioxidant formulation for the nutritional supplement formulation substantially changes and completely obliterates the indicating functions of the invention. It erroneously assumes that an indicated stable known amount of vitamin C is identical to unknown oxidizing amount(s) that cannot be indicated. And, it disregards the continual loss in effectiveness of the inherent nutrition-supplementing property and function of vitamin C due to its ongoing oxidation. The effectiveness of the nutrition-supplementing property and function of vitamin C is inseparable from its amount. So, when the amount of vitamin C is not known, its nutrition-supplementing property and function are not known either.

SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation and intended to be oxidized. So, vitamin C is oxidized unpredictably to unknown amounts that cannot be predetermined or indicated in products based on them. Oxidized vitamin C is not chemically identical to vitamin C. Its properties are not the same as vitamin C. And, its functions are not the same as vitamin C. SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose indicating supplementing nutrition or any intention of supplementing nutrition. They do not disclose a percent daily value for vitamin C. They do not disclose indicating an amount of vitamin C or indicating a percent daily value for vitamin C. They do not disclose a vitamin C formulated as a nutritional supplement, an amount of vitamin C that can be indicated, or vitamin C formulated as used by Appellant's claimed invention.

SS Pharmaceutical, Tsunoda, and Yeh et al disclose vitamin C formulated as an antioxidant without protection from oxidation and intended to be oxidized. It is continually oxidized, so its amount continually decreases and cannot be indicated. Thus they teach away from formulating a stable amount of vitamin C as a nutritional supplement. And they teach away from indicating it as an amount and percent daily

value of nutritional supplement for supplementing nutrition. And, they do not disclose any teaching to suggest their combination with Krause. Thus, the applied prior art teaches away from the feature of Appellant's claims of a nutritional supplement in a unit dose of discomfort reliever. It teaches away from indicating an amount and percent daily value of nutritional supplement in a unit dose of discomfort reliever. And, it teaches away from indicating an amount of nutritional supplement for supplementing nutrition in a unit dose of discomfort reliever.

Printed matter may well constitute limitations upon which patentability can be predicated. Indicating an amount (and percent daily value) of vitamin C is related to its new formulation as a stable amount of nutritional supplement in a unit dose of discomfort reliever that is indicated. Vitamin C formulated as a nutritional supplement and indicated by its amount and percent daily value in a unit dose of discomfort reliever is unexpectedly superior to the prior art. It requires only half of the number of compositions and containers required by the prior art. It is not taught by the prior art. And, it is not obvious from the prior art. So, it is matter that constitutes limitations upon which patentability can be predicated. The PTO must consider all claim limitations, when determining patentability of an invention over the prior art, and may not disregard claim limitations comprised of printed matter. A printed matter rejection under section 103 stands on questionable legal and logical footing.

The rejection is erroneous because it assumes that discomfort reliever labeling would include indications indicating supplementing nutrition and percent daily value, which are neither disclosed in the applied prior art or prior commercial labeling, nor mandated by drug, food or dietary supplement labeling laws. And, it erroneously asserts that it would be obvious to include indications indicating supplementing nutrition and percent daily value in a hypothetical drug label for a theoretical product, which is not intended to supplement nutrition. Thus, the rejection is unsupported, and inconsistent with the applied prior art, the law and prior commercial labeling of record.

The combination of references is not proper, because nothing is taught in them to suggest their combination. It does not meaningfully consider all of the limitations of the claims. It substantially changes and completely obliterates the indicating function of the invention. So, it does not have a reasonable expectation of success. And, it is

based on forbidden hindsight. Also, SS Pharmaceutical, Tsunoda, and Yeh et al teach away from Appellant's invention.

Appellant's invention provides the same discomfort relief, but with improved ability to self-regulate consumption of nutritional supplements over the prior art. Thus, it retains all of the functions of the prior art, while it omits half of the number of its compositions and containers. These are data of superior results, and indicia of unobviousness, over the prior art. So, patentability is shown beyond the requirements of the statute. Given the similar compositions of SS Pharmaceutical, Tsunoda and Yeh et al to those useful in Appellant's invention, the substantially improved results of Appellant's invention are *ipso facto* unexpected.

There is simplicity of the new invention, given the similarity of the compositions of SS Pharmaceutical, Tsunoda, and Yeh et al to those useful in Appellant's invention. But, the simplicity of a new invention is often the very thing that is not obvious before it is made.

Appellant's invention is not obvious over the applied prior art references. It is not mandated by law. It eliminates half of the unit dose compositions and containers required by the prior art. And, it enables consumers to self-regulate their consumption of vitamins and/or minerals while relieving a discomfort. Consumers with regular discomfort, regularly consume nutritional supplements, without having to routinely remember to find and consume them, by using Appellant's invention.

Reversal of the final rejection and allowance of the claims is respectfully requested.

Respectfully submitted,

DALE R. LOVERCHECK
Patent Attorney Reg. No. 28638
Telephone number: (610) 410-2710 December 30, 2004

APPENDIX A

211.137 Expiration dating.

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in §211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in §211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this chapter.

(e) Homeopathic drug products shall be exempt from the requirements of this section.

(f) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section.

(g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product.

(h) Pending consideration of a proposed exemption, published in the Federal Register of September 29, 1978, the requirements in this section shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years as supported by appropriate stability data.

[43 FR 45077, Sept. 29, 1978, as amended at 46 FR 56412, Nov. 17, 1981; 60 FR 4091, Jan. 20, 1995

APPENDIX B

McGRAW-HILL CONCISE ENCYCLOPEDIA OF SCIENCE & TECHNOLOGY

Second Edition

Sybil P. Parker
Editor in Chief

McGRAW-HILL PUBLISHING COMPANY

New York St. Louis San Francisco

Auckland Madrid San Juan
Bogotá Mexico São Paulo
Caracas Milan Singapore
Hamburg Montreal Sydney
Lisbon New Delhi Tokyo
London Oklahoma City Toronto
Paris

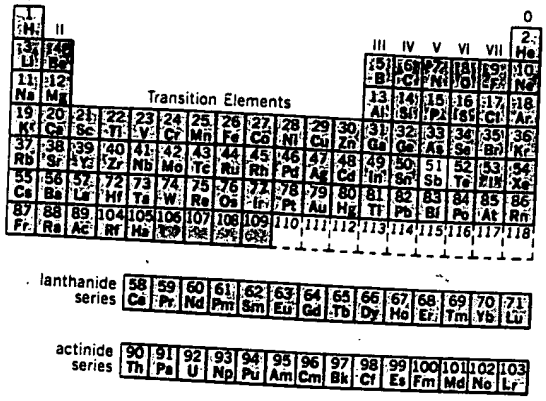
On the cover: The Great Nebula in Orion is a gas cloud excited to incandescence by hot stars in its center. The photograph was made with a 150-in. (3.8-m) telescope. (*Copyright by Anglo-Australian Telescope Board, 1981*)

1234567890 DOW/DOW 8965432109

Library of Congress Cataloging in Publication Data

McGraw-Hill concise encyclopedia of science & technology / Sybil P. Parker, editor in chief. — 2nd ed.
p. cm.
Bibliography: p.
Includes index.
ISBN 0-07-045512-0
1. Science—Dictionaries. 2. Technology—Dictionaries. I. Parker, Sybil P. II. Title: Concise encyclopedia of science & technology. III. Title: Concise encyclopedia of science and technology.
Q121.M29 1989 88-33275
503'.21—dc19

ISBN 0-07-045512-0



sionally found native, often in isomorphous mixture with arsenic, as allemonite. The symbol Sb is derived from the Latin name stibium.

The element is dimorphic, existing as a yellow, metastable form composed of Sb_4 molecules, as in antimony vapor and the structural unit in yellow antimony; and a gray, metallic form, which crystallizes with a layered rhombohedral structure. Antimony differs from normal metals in having a lower electrical conductivity as a solid than as a liquid (as does its congenor, bismuth). Metallic antimony is quite brittle, bluish-white with a typical metallic luster, but a flaky appearance. Although stable in air at normal temperatures, it burns brilliantly when heated, with the formation of a white smoke of Sb_2O_3. Vaporization of the metal gives molecules of Sb_4O_6, which break down to Sb_2O_3 above the transition temperature.

Antimony occurs in nature mainly as Sb_2S_3 (stibnite, antimonite); Sb_2O_3 (valentinite) occurs as a decomposition product of stibnite. Antimony is commonly found in ores of copper, silver, and lead. The metal antimonides NiSb (breithaupite), NiSbS (ullmannite), and Ag_2Sb (dicrasite) also are found naturally; there are numerous thioantimonates such as Ag_3SbS_3 (pyrargyrite).

Antimony is produced either by roasting the sulfide with iron, or by roasting the sulfide and reducing the sublimate of Sb_4O_6 thus produced with carbon: high-purity antimony is produced by electrolytic refining.

Commercial-grade antimony is used in many alloys (1–20%), especially lead alloys, which are much harder and mechanically stronger than pure lead: batteries, cable sheathing, antifriction bearings, and type metal consume almost half of all the antimony produced. The valuable property of Sn-Sb-Pb alloys, that they expand on cooling from the melt, thus enabling the production of sharp castings, makes them especially useful as type metal. [J.L.T.W.]

Antineutron The antiparticle (charge-conjugate particle) of the neutron. All electromagnetic properties of a particle are inverted in sign in the charge conjugate; thus the antineutron has a magnetic moment equal and opposite to that of the neutron. Mass, spin, and the decay constant for beta decay are identical for the antineutron and the neutron. Both are fermions of spin 1/2. *See* ELEMENTARY PARTICLE; NEUTRON. [E.G.S.]

Antioxidant An inhibitor which is effective in preventing oxidation by molecular oxygen (autoxidation). Such inhibitors have great commercial significance in the preservation of food and food products and in the prevention of deterioration of petroleum products, rubber, and plastics.

Autoxidations are free-radical chain reactions characterized by the interaction of the radicals with oxygen to yield peroxy radicals, organic peroxides, and a broad spectrum of stable oxygenated products. Autoxidation chains are often long, so that a single initiating event may produce many stable product molecules. Thus only a very small amount of an effective antioxidant need be employed for the protection of a large quantity of a substrate. The role of the antioxidant is to provide an alternate path for oxidation which does not involve the substrate. The antioxidant is destroyed in the process and thus does not function indefinitely.

The major types of antioxidants in use are the phenols, the aromatic amines, sulfur compounds, and a variety of naturally occurring materials. The latter find particular use in the protection of foods and cosmetics from oxidation. Naturally occurring antioxidants include raw seed oils, wheat germ oil, tocopherols, and gums. The activity of the last-named category may often be increased by the use of synergists. These are substances which have little or no activity alone but which enhance the activity of stronger antioxidants. Some effective synergists are phosphoric, citric, and ascorbic acids.

The wide variety of antioxidants available is necessitated by the extreme range of conditions under which protection from oxidation is required. For example, an antioxidant which can delay the development of rancidity in stored butter will seldom prove to be suitable for the protection of hot lubricating oil in the crankcase of an automobile. *See* CATALYSIS; FREE RADICAL; INHIBITOR (CHEMISTRY). [L.R.M.]

Antipatharia An order of the subclass Zoantharia. These animals are the black or horny corals which live in rather deep tropical and subtropical waters and usually form regular or irregularly branching plant-like colonies, often 6.6 or 9.9 ft (2 or 3 m) in height, with thorny, solid lamellar, horny axial skeletons (see illustration). *Stichopathes* forms an unbranching wirelike colony.

Antipathes rhipidion. (*After F. Pax*)

The polyp or zooid has six unbranched, nonretractile tentacles with a warty surface due to the presence of nematocysts. Six primary, complete, bilaterally arranged mesenteries occur, of which only two lateral ones bear filaments and gonads. Adjacent zooids are united by a coenenchyme, but their gastrovascular cavities have no connection. The musculature is the most weakly developed in the anthozoans.

The polyps are dioecious. Schizopathidae are dimorphic; the gastrozooid has a mouth and two tentacles, while the gonozooid, the only fertile polyp, lacks a mouth. *See* COELENTERATA; ZOANTHARIA. [K.AL.]

Antiproton The antiparticle (charge-conjugate particle) of the proton. P. A. M. Dirac's equation of relativistic quantum theory for the electron admits solutions which describe a particle of mass identical to that of the electron but of opposite charge; this is the positron. A generalization of the relativistic

THE REAL VITAMIN & MINERAL BOOK

SHARI LIEBERMAN, PhD
AND NANCY BRUNING

Avery Publishing Group
Garden City Park, New York

Cover Design: William Gonzalez and Rudy Shur
In-House Editor: Joanne Abrams
Printer: Paragon Press, Honesdale, PA

Cataloging-in-Publication Data
Lieberman, Shari.
The real vitamin and mineral book: using supplements for optimum health / Shari Lieberman, Nancy Bruning.—2nd ed.
p. cm.
Includes bibliographical references and index.
ISBN 0-89529-769-8

1. Vitamins—Popular works. 2. Minerals in the body—Popular works. I. Bruning, Nancy. II. Title.

QP771.L543 1997612.3'99
QBI96-40554

Printed in the United States of America

10 9 8

CONTENTS

Chapter 1

WHAT ARE VITAMINS AND MINERALS?

Vitamins and minerals are nutrients that are essential to life. They are often called *micronutrients* because, in comparison with the four major nutrients—carbohydrates, proteins, fats, and water—they are needed in relatively small amounts.

Vitamins are organic compounds, meaning that they occur naturally in plants and animals. By and large, vitamins function as *coenzymes*. Enzymes are catalysts or activators in the chemical reactions that are continually taking place in our bodies. Vitamins are a fundamental part of the enzymes, much the way your muscles are a fundamental part of your arms and legs.

Most people are aware that our enzymes help us digest our food. But enzymes do more than digest food. They are at the very foundation of *all* our bodily functions. Enzymes are what make things happen, and happen faster. Without enzymes, you can't breathe, blink, or walk. Your body can't break down proteins into essential amino acids, electrons can't flow, and nerve transmissions can't occur. You can't pull your hand out of the fire (or put it there in the first place), smell a rose, see a sunset, or taste an apple. And without vitamins, the enzymes can't do their job. For example, consider a particular enzyme that is needed to transmit nerve impulses to your fingers. No matter how plentiful this enzyme is in your body, if you are deficient in B_6, this enzyme cannot be activated. As a result, you might feel some numbness in your fingers.

Minerals are inorganic elements, meaning that they are not produced by plants and animals. Like vitamins, many minerals function as coenzymes, enabling chemical reactions to occur throughout the body.

In addition to their role as coenzymes, some micronutrients have other functions. For example, vitamin E acts as an antioxidant; calcium, magnesium, and phosphorus form our bones; iron enables the transport of oxygen from the lungs to the body cells; and active vitamin D functions as a hormone.

After they have been absorbed, vitamins and minerals actually become part of the structure of the body—of the cells, enzymes, hormones, muscles,

Chapter 3

THE OPTIMUM DAILY INTAKES (ODIs)

Recent evidence indicates that most of the RDIs are far too low. Why? Because vitamins and minerals do more than just prevent the severe, overt symptoms that are traditionally associated with deficiencies. Remember: *Vitamins and minerals are used in every process of the body.* We now know, for example, that vitamin A does more than prevent night blindness, that thiamin prevents more than beriberi, and that vitamin C does much more than prevent scurvy. By optimizing our daily intake of nutrients, we don't simply prevent disease. We help ensure a state of optimal health.

SUBCLINICAL DEFICIENCIES

State-of-the-art biochemistry shows that classic, overt deficiency symptoms, like those of beriberi, are merely the last event in a long chain of reactions in the body, the way an erupting volcano or earthquake is the last dramatic step in a series of underground processes. That we are not always aware of these processes does not mean that they do not exist, or that they will not eventually cause an explosion of ill health at some point in the future. When we do not get enough of a specific vitamin, the initial reactions occur on the molecular level. The first thing that happens is a depletion of the vitamin stores in the body. Then the enzymes, of which the vitamin is a part, become depleted. This, in turn, brings about changes on the cellular level: Some of the cells of the body, which depend upon these enzymes, can no longer carry out their normal functions. It is not until the depletion is prolonged and severe that the classic clinical signs of deficiency appear.

Such cellular changes are also known as *subclinical deficiencies* because they are not the kind of deficiencies that your doctor would necessarily discover through a routine physical exam and blood tests. But while they may not be obvious, easily definable, or immediately debilitating, these deficiencies *do* have an effect on the body's well-being. For example, volunteers who were depleted of vitamin B_1 showed no detectable body changes for the first five to ten days. After ten days, there was evidence of changes in the cells'

metabolism. Classic anatomical signs of B_1 deficiency became obvious only after about two hundred days. However, during that time, the subjects experienced a gradual decline in their health with nonspecific symptoms of loss of weight, loss of appetite, general malaise, insomnia, and irritability.

The subtle, subclinical changes due to poor nutrition may be responsible for a broad range of diffuse, nonspecific conditions that can at first be merely annoying and reduce our overall health and quality of life. These conditions can include chronic fatigue, skin problems, recurrent or lingering infections and colds, digestive problems, sleep problems, headaches, hormonal problems, depression, and nervousness. Poor nutrient intake may also leave us more vulnerable to genetically predisposed diseases and conditions such as cardiovascular disease, diabetes, and cancer. The role that the other nutrients, such as fat and carbohydrates, play in these diseases is becoming more and more solidly documented. Why should we be surprised by the accumulating evidence that vitamins and minerals also play a part?

NUTRITION—NATURE'S PROTECTOR

As already discussed, nutrients do far more than protect the body against deficiency diseases. By buttressing our immune system, they protect us from foreign invaders, and therefore help fight infection. By guarding us from the ravages of oxidative stress, they prevent or slow the progress of a variety of degenerative illnesses, including cancer. And by helping regulate the balance of fats in the body, they fight heart disease. A brief look at each of these functions will provide a clearer idea of the importance of optimum nutrient intake to good health.

Nutrients and the Immune System

Our immune system is a complex system of blood cells and special proteins acting together to defend us from harm. Improving our immune defense system is the main thrust behind modern preventive medicine because it protects us in so many important ways. For example, the immune system has the ability to engulf and kill bacteria and viruses. It can also repair or destroy a damaged cell before it grows into a cancerous tumor. This system, though powerful, is extremely delicate, its parts exquisitely interdependent upon one another. If any one aspect is compromised, we may become more susceptible to infections; degenerative diseases such as cancer and diabetes; and, perhaps, cardiovascular disease and certain forms of arthritis.

In many studies, inadequate nutrition has been shown to weaken one or more of the components of our defense system. Insufficient protein, too little fiber, and too much fat have all been implicated in impaired immunity, as have vitamin and mineral deficiencies. On the other hand, excesses of the